

## REMARKS

Claims 15-17, 21-26, 28, and 29 are pending in the application. Claims 15-17, 21-26, 28, and 29 stand rejected. As intimated in the Office Action of January 22, 2003, claims 31-50, relating to methods of diagnosing Lyme disease and methods of producing FlaA protein, have been added. Support for the claim amendments and additions can be found throughout the specification as filed, particularly on pages 5 and 6.

The Applicants wish to thank the Examiner for the courtesy shown to Lisa Hillman and Emily Miao during the interviews conducted on November 7, 2002 and on April 15, 2003. The Applicants note that the amendment filed October 23, 2002, was acknowledged in the Office Action and that the amendment has been entered. The Applicants also note that all prior rejections have been withdrawn in view of the applicants' amendment. The Applicants further note that the pending Office Action is non-final.

Claims 15-17, 21-26, 28, and 29 stand rejected under 35 U.S.C. § 102(a or b) as being anticipated by Ge *et al.*, 1997 (J. Bacteriology). The Applicants traverse the rejection for the reasons that follow.

### **Rejection of claims 15-17, 21-26, 28, and 29 under 35 U.S.C. § 102(a or b)**

Claims 15-17, 21-26, 28, and 29 stand rejected under 35 U.S.C. §102(a or b) as allegedly being anticipated by Ge *et al.* 1997 (J. Bacteriology; "Ge I"). Applicants respectfully traverse the rejection.

The Examiner asserts that instant application is directed to recombinant FlaA protein. The Examiner further asserts that Ge *et al.* discloses a *B. burgdorferi* FlaA protein. The Examiner also asserts that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art. The Examiner still further asserts that if the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner also indicates that the Office Action of January 22, 2003 focuses

Immunity, 68:2992 (1997), ("Ge II"), of record. Neither Ge I nor Ge II, nor the combination of

the two, anticipate the invention because they do not teach the diagnostic reagent as claimed in the present invention. Ge I does not disclose, explicitly or impliedly, the utility of FlaA protein as a diagnostic reagent. Ge II expressly teaches against the use of FlaA protein in diagnosing Lyme disease. Ge II concluded:

**FlaA is not an immunodominant antigen** in Lyme disease. (second column, heading, p. 2993)(emphasis added)

and

...FlaA is a protein unique to spirochetes, our results suggest that it **is not a good candidate** for the serodiagnosis of Lyme disease. (second column, last sentence, p. 2994)(emphasis added).

Ge II could not more clearly teach that FlaA is unsuitable as an antigen in a test kit or diagnostic test for Lyme disease than in the title of the article: "**FlaA, a Putative Flagellar Outer Sheath Protein, Is Not an Immunodominant Antigen Associated with Lyme Disease.**" Therefore, according to the of-the-record teachings of Ge *et al.*, FlaA protein is unequivocally not a diagnostic reagent. That is, the present invention is directly taught against by Ge *et al.*, collectively. Applicant respectfully suggests that the Examiner is neglecting a reference of record (Ge II) to bolster her arguments because Ge II inconveniently teaches against the present invention, which relates to, among other things, FlaA-related diagnostic reagents and methods of diagnosing Lyme disease. That is, contrary to the Examiner's conclusion, Applicants are not claiming the discovery of the "recombinant FlaA protein" but rather a "diagnostic test" utilizing FlaA to detect early Lyme disease. That FlaA is suitable for use in a diagnostic test for Lyme disease is exactly what Ge II teaches against.

The Examiner further asserts that the Applicants' recitation of "A diagnostic reagent for early detection of Lyme disease" is not entitled to any patentable weight due to its location in the preamble. The preamble of the present claims is not merely a statement of purpose or use but also gives the claim meaning and scope. Applicants' preamble is significant because it defines their invention. *Kropa v. Robie and Mahlman*, 88 USPQ 478, 481 (CCPA 1951) (a preamble is given the effect of a limitation where the introductory words "give life and meaning" to the subject matter defined by the claims). Anticipation was not found where without the essential

the preamble ("an optical waveguide") was a limitation in the claim. Sumitomo argued that the structure recited in the claim at issue was identical to a previously disclosed conventional fiber structure.

If the claims were given the Sumitomo's suggested interpretation, i.e., the preamble language had no effect or limitation, then the claims would be anticipated by the previously disclosed conventional fiber structure, otherwise they were not. *Id.* Like the optical waveguide in the Corning case, the preamble in the instant case is the subject matter being worked on to solve the problem of providing an effective test for diagnosing early Lyme disease. A claim preamble should be given importance as part of the claim if the preamble, in conjunction with the body of the claim defines "one unified and internally consistent recitation of the claimed invention." *Pitney Bowes, Inc. v. Hewlett Packard Co.*, 51 USPQ2d 1162, 1166 (Fed. Cir. 1999) Claims 15-17, 21-26, 28, and 29 are defined by both the preamble and the claim body together directed to a diagnostic reagent utilizing a recombinant FlaA protein, and not solely a recombinant protein.

Whether preamble recitations are considered additional structural limitations, statements of use or mere introductory language is determined by examining the entire record for the intended invention sought to be claimed. *Corning Glass Works*, 9 USPQ2d at 1966. As further support of the intended invention, the entire specification sets forth detail specifically teaching a recombinant FlaA protein as an effective reagent in a test kit. Here, both the specification and claims define the intended invention, a diagnostic reagent including FlaA. Thus, to read the claims and specification separately, as the Examiner has done, is to dismiss the subject matter of the specification and substitute incorrect subject matter for what is claimed, which is improper.

More specifically, Ge I does not teach a diagnostic reagent. Ge I does not disclose that FlaA is a diagnostic reagent and the follow-up article, Ge II, specifically teaches that FlaA is not a diagnostic reagent for Lyme disease. The instant invention, with the assistance of the preamble, claims a diagnostic reagent. Importantly, "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v.*

determined on the facts of each case in light of the overall form of the claim, and the invention as

described in the specification and illuminated in the prosecution history.” *Applied Materials, Inc. v. Advanced Semiconductor Materials*, 40 U.S.P.Q.2d 1481, 1488 (Fed. Cir. 1996). Additionally, “clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.” *Catalina Marketing Int'l Inc. v. Coolsavings.com Inc.*, 67 U.S.P.Q.2d 1781, 1785 (Fed. Cir. 2002).

The instant application and prosecution history clearly reveal that the invention is the surprising discovery, contrary to the teachings of the prior art, that FlaA is indeed a diagnostic reagent. Therefore, because the instant application and prosecution history clearly rely on the preamble, the preamble is properly given patentable weight in this case. Ge I, in view of the teachings of Ge II, does not teach a FlaA diagnostic reagent. Therefore Ge I cannot anticipate the instant claims. Neither Ge I nor Ge II or even the combination of these references anticipate the invention because they do not teach a diagnostic reagent as claimed in the present invention. Ge I does not disclose, expressly or impliedly, the utility of FlaA protein as a diagnostic reagent.

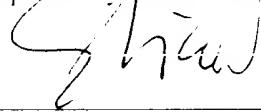
Every limitation of a claimed invention must be taught, either explicitly or inherently, within a single prior art reference in order to find anticipation or lack of novelty under 35 USC §102(a). *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), *Glaxo Inc. v. Novopharm Ltd.*, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995). As established above, such is not the case regarding Ge *et al.*, collectively. Consequently, the Examiner has not met a *prima facie* burden to show each and every element of the claims in Ge I or Ge II.

In view of the amendments to the claims and the remarks above, the applicants respectfully request that the rejection of claims 15-17, 21-26, 28, and 29 under 35 U.S.C. § 102 (a or b) be reconsidered and withdrawn.

## CONCLUSION

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Patent Office is invited to contact the undersigned representative if it is believed that this would be helpful in expediting prosecution of this application. The applicants assert that the pending claims are allowable; prompt issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,



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